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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,838	09/23/2005	Juli Yamashita	5703-010/NP	6048
27572 7590 12/26/2007 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER CARLOS, ALVIN LEABRES	
			ART UNIT 3714	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/550,838

Applicant(s)

YAMASHITA ET AL.

Examiner

Alvin L. Carlos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/13/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/23/2005, 06/02/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The listing of references in the Search Report dated 9/23/2005 is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirikae 4209919.

Re claim 1, Kirikae teaches a replica comprising a thin bone part being reproduced with physical properties close to those of real tissue (column 1 lines 38-40). In addition, considering the thin bone part having a thickness of not more than 0.1 mm, since the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” **In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235**

Re claim 2, Kirikae teaches a replica comprising soft tissue being reproduced with physical properties close to those of real tissue (column 41-48).

Re claim 3, Kirikae teaches a part of replica is a breakable part that can be irreversibly broken during surgical manipulation (See figure 1, column 4 lines 22-32).

Re claim 4, Kirikae teaches a breakable part is replaceable (See figure 1 and 7, column 4 lines 33-39).

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Re claim 8, Kirikae teaches a part of said replica is a breakable part that can be irreversibly broken during surgical manipulation (See figure 1, column 4 lines 22-32).

3. Claims 5-7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirikae 4209919 in view of Swaelens 5768134.

Re claim 5, Kirikae teaches the invention as discussed above.

However, Kirikae fails to teach the following limitations as taught by Swaelens: a production method for a replica (column 1 lines 7-14), comprising creating shape data concerning a thin bone part by CAD (column 4 lines 5-8), and rapid prototyping thin bone part on a basis of shape data, thereby reproducing a part of a human body (column 3 lines 64-67 and column 4 lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kirikae's invention in view of Swaelens in order to provide a method for making a medical model on the basis of digital image information of a body part whereby the image information can be optimally used and can be put to use in practice as taught by Swaelens (column 2 lines 37-41).

In addition, considering the thin bone part having a thickness of not more than 0.1 mm, since the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." **In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235**

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Re claim 6, Kirikae teaches the invention as discussed above. In addition, Kirikae teaches forming a resin coating on thin bone part (column 2 lines 14-18).

However, Kirikae fails to teach the following limitations as taught by Swaelens: rapid prototyping thin bone part (column 3 lines 64-67 and column 4 lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kirikae's invention in view of Swaelens in order to provide a method for making a medical model on the basis of digital image information of a body part whereby the image information can be optimally used and can be put to use in practice as taught by Swaelens (column 2 lines 37-41).

Re claim 7, Kirikae teaches the invention as discussed above. In addition, Kirikae teaches a part of the human body is a paranasal sinus region (see figure 1, column 2 lines 41-43).

Re claim 9, Kirikae teaches the invention as discussed above. In addition, Kirikae teaches a part of the human body is a paranasal sinus region (see figure 1, column 2 lines 41-43).

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as per the attached Notice of References Cited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin L. Carlos whose telephone number is 571-

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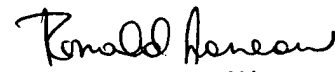
2703077. The examiner can normally be reached on 7:30am-5:00pm EST Mon-Fri (alternate Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571) 272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



12/12/2007



RONALD LANEAU  
PRIMARY EXAMINER

12/19/07